Complete Summary

GUIDELINE TITLE

Asthma.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. UMHS asthma guideline. Ann Arbor (MI): University of Michigan Health System; 2000 Jan. 14 p. [14 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

SCOPE

DISEASE/CONDITION(S)

IDENTIFYING INFORMATION AND AVAILABILITY

Asthma

GUIDELINE CATEGORY

Diagnosis Evaluation Management

CLINICAL SPECIALTY

Allergy and Immunology Emergency Medicine Family Practice Gastroenterology Internal Medicine Nursing Pediatrics

INTENDED USERS

Advanced Practice Nurses Nurses Pharmacists Physician Assistants Physicians Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

To improve the patient's quality of life by achieving and maintaining control of symptoms; attaining normal lung function; minimizing need for as-needed beta2-agonists; avoiding adverse effects from asthma medications; preventing exacerbations; attaining normal activity levels, including exercise; and preventing emergency visits and hospitalizations.

TARGET POPULATION

Children, adolescents, and adults with asthma.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

- 1. Physical examination and patient history (to determine if symptoms and signs of asthma are present and exclude alternative diagnoses)
- 2. Objective measurements of airway obstruction (spirometry)

Management

- 1. Education of patients to develop a partnership in asthma management.
- 2. Assessment of asthma severity with objective measures of lung function (Peak Expiratory Flow Rate [PEFR] Monitoring)
- 3. Avoidance or control of asthma triggers:
 - Indoor allergens (domestic mites, animal allergens, cockroach allergens, fungi, occupational allergens and irritants)
 - Outdoor allergens (pollens, molds)
 - Food additives (sulfites, tartrazine [yellow dye], parabens, monosodium glutamate)
 - Indoor air pollution (tobacco or other smoke, air pollutants)
 - Medications (aspirin, nonsteroidal anti-inflammatory drugs [NSAIDs], beta-blockers)
 - Exercise
 - Concurrent medical conditions (infections [e.g., viral upper respiratory infection, bronchitis, sinusitis], allergic rhinitis, gastroesophageal reflux disease)
- 4. Establishment of medication plans for chronic management
 - Anti-inflammatory medications:
 - Inhaled corticosteroids: Beclomethasone, MDI (Metered Dose Inhaler) (Beclovent, Vanceril, Vanceril DS); Budesonide, DPI (Dry Powder Inhaler) (Pulmicort, Turbuhaler); Triamcinolone,

- MDI (Azmacort); Flunisolide, MDI (Aerobid); Fluticasone, MDI (Flovent); Fluticasone, DPI (Flovent Rotadisk)
- Systemic corticosteroids: Prednisone, Prednisolone, Methylprednisolone
- Leukotriene modifier agents: Montelukast (Singulair),
 Zafirlukast (Accolate), Zileuton (Zyflo)
- Non-steroidal drugs with anti-inflammatory properties (mast cell stabilizers): Nedocromil sodium, MDI (Tilade); Cromolyn sodium, MDI (Intal)
- Bronchodilator medications:
 - Inhaled, short-acting beta2-agonists: Albuterol, MDI (Proventil, Ventolin, Proventil HFA); Albuterol, DPI (Ventolin, Rotahaler); Bitolterol, MDI (Tornalate); Pirbuterol, MDI (Maxair); Terbutaline, MDI (Brethaire)
 - Inhaled, long-acting beta2-agonists: Salmeterol, MDI (Serevent); Salmeterol, DPI (Serevent Diskus)
 - Methylxanthines: Theophylline (e.g., Theodor, Uniphyl, Slophyllin)
 - Anticholinergics: Ipratropium, MDI (Atrovent)
 - Use of bronchodilators: pediatric considerations and home nebulizers
- 5. Establishment of plans for managing exacerbations
- 6. Regular follow-up care and consideration of consultation or referral

MAJOR OUTCOMES CONSIDERED

- Symptom relief
- Patient quality of life
- Drug interactions and side effects
- Morbidity associated with asthma

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developers identified relevant data via a MEDLINE (U.S. National Library of Medicine) search that included the following terms: asthma, peak flow meter, spirometry, diagnosis, treatment, randomized controlled trials, practice guidelines.

The guideline developers also reviewed literature referenced in the National Asthma Education Program's "Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma" (Bethesda [MD]: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung and Blood Institute; 1997 Jul), and the "International Consensus

Report on Diagnosis and Treatment of Asthma" (Bergner A, Bergner RK. The international consensus report on diagnosis and treatment of asthma: a call to action for US practitioners. Clin Ther 1994 Jul-Aug; 16(4):694-706; discussion 693).

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE FVI DENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of evidence for the most significant recommendations:

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Decision analysis
- D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials (RCTs) if available, to the exclusion of other data; if RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by leadership in departments to which the content is most relevant. This guideline concerning asthma was reviewed by members of the following departments: Allergy; Emergency Medicine; Family Medicine; General Internal Medicine; Pediatrics & Communicable Diseases; Pharmacy; Pulmonary & Critical Care Medicine.

Guidelines are approved by the Primary Care Executive Committee (PCEC) and the Executive Committee of Clinical Affairs (ECCA).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on diagnosis, six-part asthma management program, dosing and cost of drugs as well as charts for predicted average peak expiratory flows.

The levels of evidence [A-D] are defined at the end of the Major Recommendations.

- A high index of suspicion for asthma is essential. A history of both symptoms and symptom triggers should be obtained. [C*]
- Objective evaluation of airflow obstruction is key to the diagnosis, classification, and management of the disease. Goals of treatment should include not only symptomatic relief, but normalization of lung function. [C*]
- Therapy should focus on long-term suppressive therapy. Antiinflammatory agents (in particular inhaled corticosteroids) are the cornerstone of therapy for moderately and severely affected patients. Inhaled beta2-agonists should represent "rescue" agents in most instances. [B*]
- Patient education should emphasize how to identify and avoid environmental triggers of asthma and smoking cessation. Patients with moderate or severe asthma should be able to measure their peak expiratory flow rate (PEFR) at home and modify their therapy or seek help based on their performance relative to their personal best peak flow value. Selfmanagement is fundamental to successful therapy. [A*]

*Definitions

Levels of evidence for the most significant recommendations:

- A. Randomized controlled trials
- B. Controlled trials, no randomization

- C. Decision analysis
- D. Opinion of expert panel

CLINICAL ALGORITHM(S)

An algorithm is provided in the guideline document for the management of asthma.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVI DENCE SUPPORTING THE RECOMMENDATIONS

This guideline was adapted from the National Heart, Lung, and Blood Institute guideline titled "Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma" (Bethesda [MD]: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung and Blood Institute; 1997 Jul).

The type of evidence for each recommendation is given in brackets following the recommendation (see "Major Recommendations).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Patients with asthma gain symptomatic relief and functional benefit from several classes of anti-inflammatory and bronchodilator medications and from education in self-management of the disease.

Subgroups Most Likely to Benefit:

- There is a subset (perhaps 5-10%) of adult asthmatics for whom cromolyn is more effective than other agents or who derive additional benefit to that obtained from maximal tolerated doses of inhaled corticosteroids, beta2-agonists, and methylxanthines.
- For patients experiencing difficulty with traditional MDI (Metered Dose Inhaler) technique, other beta2-agonist options include use of rotocaps (dry powder inhalers) or autoinhalers (breath-activated MDIs).
- Patients who chronically do not adhere to their treatment regimen may benefit from an intensive asthma health behavior/health education intervention.

POTENTIAL HARMS

Side effects associated with pharmacotherapy:

- 1. Anti-inflammatory agents
 - Inhaled corticosteroids
 - There is a dose-dependent reduction of short-term growth with the use of conventional doses of beclomethasone dipropionate.

- Inhaled corticosteroids in doses as high as 800 mcg/d exert much less short-term growth suppression than low-dose oral corticosteroids.
- High doses of inhaled corticosteroids may cause systemic side effects (though to a much lesser extent than oral steroids will). Risk of side effects with high-dose inhaled steroids can be minimized by having the patient rinse his/her mouth immediately after inhalation and before swallowing and by using a spacer device.
- Systemic corticosteroids
 - Chronic systemic corticosteroid therapy may be associated with obesity, moon facies, supraclavicular and nuchal fat pads, striae, easy bruisability, weakness, hypertension, and glucose intolerance.
 - Long-term (>2 weeks) corticosteroid therapy may cause suppression of the hypothalamic-pituitary-adrenal axis. Full recovery of the axis can take up to 12 months depending on the dose, frequency, and duration of antecedent therapy. Adrenal insufficiency can evolve into acute adrenal crisis precipitated by severe infection, trauma, or surgery.
 - Systemic corticosteroid therapy can cause osteopenia.
- Leukotriene modifier agents
 - The U.S. Food and Drug Administration (FDA) mandates monitoring hepatic enzymes with use of the 5-lipoxygenase-inhibitor zileuton.
 - Churg-Strauss Vasculitis has rarely been reported in association with montelukast or zafirlukast in patients tapering chronic systemic corticosteroids.
- 2. Inhaled, short-acting beta2-agonists: Several epidemiologic studies have found an association between excess use of beta2-agonist inhalers and asthma mortality. A causal relationship has not been demonstrated, and it is possible that beta2-agonists represent a mere marker for the severity of disease, being more frequently prescribed for patients with life-threatening asthma. If beta2-agonists do have a causative role, it may be an indirect one, such as delaying presentation until airway obstruction is more severe.

Drug interactions:

Leukotriene modifier agents: Both zafirlukast and zileuton can potentiate warfarin and theophylline as well as interact with several other medications.

Subgroups Most Likely to be Harmed:

- 1. Anti-inflammatory agents
 - Long-term linear growth does not appear to be affected by moderate doses (400-800 mcg/day) of inhaled corticosteroids, except in prepubertal males.
 - Children may exhibit growth failure from chronic systemic corticosteroid therapy.
 - In pregnancy, both leukotriene receptor antagonists zafirlukast and montelukast are category B while zileuton is category C.

2. Beta2-agonists: Safety and efficacy of the inhaled, long-acting beta2-agonist salmeterol has not been established in children less than 12 years of age.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgement regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. UMHS asthma guideline. Ann Arbor (MI): University of Michigan Health System; 2000 Jan. 14 p. [14 references]

ADAPTATION

This guideline was adapted from the National Heart, Lung, and Blood Institute "Expert panel report 2: guidelines for the diagnosis and management of asthma". Bethesda (MD): U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung and Blood Institute; 1997 Jul.

DATE RELEASED

1996 Dec (revised 2000 Jan)

GUI DELI NE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

Internal funding for University of Michigan Health System (UMHS) guidelines is provided by the Office of Clinical Affairs. No external funds are used.

GUIDELINE COMMITTEE

Asthma Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members: Lee Green, MD MPH (Team Leader); James Baldwin, MD; Steve Erickson, Pharm.D.; Cyril Grum, MD; Martin Hurwitz, MD; Sonya Mitrovich, MD; John Younger, MD.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Neither members of the Asthma Guideline Team nor members of the Guideline Oversight Team have relationships with commercial companies whose products are discussed in this guideline.

GUI DELI NE STATUS

This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies of the updated guideline: Available from the <u>University of Michigan Health System Web site</u>. Continuing Medical Education (CME) information is also available.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

 Asthma-Patient Action Plan: a written action plan based on signs and symptoms to help patients with self-management. Ann Arbor (MI): University of Michigan Health System, 1999. Print copies: Available from the University of Michigan Health System, GUIDES, 300 North Inglass, Room 7A10, Ann Arbor, MI 49109-0826; Telephone: (734) 936-9771; Fax: (734) 615-0062; e-mail: gdlnoversight@umich.edu.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on August 21, 2000. The information was verified by the guideline developer on November 22, 2000.

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